Exhibit 2

Clayman & Rosenberg LLP

305 Madison Avenue
New York, NY 10165
T: 212-922-1080
F: 212-949-8255

Henry E. Mazurek
Partner
mazurek@clayro.com

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Via Email

Brooke E. Cucinella
Edward B. Diskant
Assistant United States Attorneys
Southern District of New York
One St. Andrew's Plaza
New York, New York 10007

Re: *United States v. Moshe Mirilishvilli, et al.,* 14 Cr. 810 (CM)

Dear Ms. Cucinella and Mr. Diskant:

Pursuant to Fed. R. Crim. P. 16(b)(1)(C), Defendant Moshe Mirilashvili hereby makes the disclosures set forth below concerning the expert testimony he expects to offer at trial. Dr. Mirilashvili reserves his right to modify and supplement these disclosures, including based upon the evidence presented in the government's case-in-chief at trial or upon further review of the sources and materials discussed here, or other relevant source materials. Also, Dr. Warfield is reviewing the patient files the parties jointly put on notice for trial and as soon she completes her review and Dr. Gharibo's findings, we will submit a summary of her expected responses.

Dr. Carol Warfield is a board certified medical doctor in the specialties of Anesthesia and Pain Medicine. Her C.V. was previously produced to you and her qualifications are fully reflected therein. Dr. Warfield's opinions will be based upon her training and experience, through which she is familiar with the evaluation of medical practitioner prescribing practices and overall medical care by medical professionals. She is also familiar with the difference between evaluating a physician for a departure from "best practices," "average," "below average," or "malpractice," and whether a practitioner acted outside the usual course of professional practice such that he was no longer practicing medicine. Dr. Warfield's conclusions will also be based upon her review of the exchanged medical records between parties. In addition, Dr. Warfield may rely on the clinical literature cited in her CV and other leading treatises and medical regulations in rendering her opinions.

Dr. Warfield is expected to provide an overview of pain management and chronic opioid therapy. She will testify that pain medicine is an area of medical practice, long the subject of fierce debate within the medical arena, concerning applicable and best practices and evidence-based medicine standards. She will testify that even today – as was the case during the time charged in this Indictment from 2012 through 2014 – there remains a lack of consensus in many areas of pain management, including how best to manage long-term chronic patients. She will testify about how experts in the field continue to disagree on how best to handle challenges presented by such patients.

She will also testify about the terminology used in the medical profession for the purpose of evaluating a medical professional's work. She will discuss conduct that is consistent with "generally accepted practices" in the medical management of pain and what conduct falls within the usual course of professional medical practice and exercise of medical judgment. Dr. Warfield will also explain how "generally accepted practices" are broader and incorporate more flexibility than the standard of care of "best practices" or "evidence-based medical standards" ("EBMS"). She will define and explain these terms based upon medical scholarship and the work of experienced practitioners. Specifically, "best practices" is a general phrase used to describe a process of infusing medical practice with research-based knowledge. "Best practices" are usually created and advocated by formal medical societies, medical licensing boards, and medical institutions, such as a hospital pain clinic. The current definition typically used for "evidence-based medical standards" is a systematic approach to clinical problem solving, which allows the integration of the best available research evidence with clinical expertise and patient values. (Citing Sackett DL, Strauss SE, Richardson, WS, *et al.*, "Evidence-based Medicine: How to Practice and Teach EBM": London: Churchill-Livingstone 2000). Dr. Warfield will explain that there are still very few evidence-based medical standards in the medical management of chronic pain.

In distinguishing the different levels of standards of care within medicine, she will use an illustration that depicts various grades of patient care. (This chart is attached at Exhibit A.) She will use the chart to help distinguish the more general standard of usual course of professional practice from Dr. Gharibo's reliance on "best practices" in his proffered testimony. (*See* Gov. Expert Discl. Ltr., 2/15/16, at 2: "Dr. Gharibo will then explain the best practices with respect to a physical examination . . ."; "it is also best practices to carefully monitor the quantity of pills prescribed to a patient in a month"; *id.*, at 4; "outside of the accepted standards of care"; *id.*, at 5; "it is best practices to prescribe a low dosage." *Id.*, at 5.)

Dr. Warfield will explain that the "standard of care" phrase referred to in Dr. Gharibo's testimony is the phrase used in civil litigation to describe the negligence standard and may be evaluated by reference to "best practices" or "evidence-based medical standards." She will testify that these definitions should not be applied to "generally accepted practices" in medicine for purposes of evaluating whether a pain

medicine doctor acted within the usual course of professional practice and indicated the use of reasonable medical judgment, as opposed to not practicing medicine at all.

She will also explain the existing state of "generally accepted practices" in pain management during the years of 2012 to 2014. The doctor will testify that during this time only general guidelines and statements existed regarding the general aspect of the medical management of pain. She will offer testimony that no specific regulations or requirements of pain management doctors exist on how to deal with specific patient challenges of addressing toxicology reports, or how to deal with pain patients who had histories of substance-abuse, or how and when to discharge patients who are on long-term opioid treatment. While some State Medical Boards have proposed Guidelines for dealing with some of these issues, there remain no firm EBMS for how to treat patients with chronic pain or how and when to respond to the very challenging clinical dilemmas presented by this patient population.

Dr. Warfield will define the differences between "opioid-naïve" and "opioid-tolerant" patients and how these differences manifest themselves in general prescribing practices. She will testify that there are no requirements to cease opioid prescriptions for those patients on long-term opioid therapy, and in fact, there are Guidelines and recommendations to continue this treatment if the patient is performing well, *i.e.*, with adequate functionality, decreased pain, and lack of side effects. Prescribing doctors are acting within the usual course of professional practice if they are monitoring the safety and effectiveness of ongoing treatment. Pain management doctors also retain discretion to determine effective dosages given the past medical history, tolerance levels, and the doctor's clinical experience in managing moderate to severe levels of pain conditions.

Dr. Warfield will testify that long-term use of opioids for management of chronic pain was within the usual course of professional pain management practices during the times charged in the Indictment. She will testify that there are no EBMS or regulations that restrict a pain management doctor from prescribing opioids for long-term care based on a patient's level of anxiety, or the subjective findings of a doctor that the patient is mentally ill-suited to maintain an opioid regimented medicine schedule, or based on any other social or psychological norm. These are all clinical judgments that, according to generally accepted practice standards, still reside within the discretion of the prescribing pain management doctor. Likewise, there were no existing regulations in 2012-2014 that restricted pain management doctors from putting a new patient, who is diagnosed with moderate to severe pain, on opioid therapy.

Dr. Warfield will further testify that the usual practice of pain medicine professionals does not require them to challenge or investigate patient statements or documents presented by the patient. She will opine that she has been fooled by patients in past experience and there are no medical requirements or regulations for doctors to conduct affirmative investigations to check on patient statements or referrals.

Dr. Warfield will opine about Dr. Mirilashvili's general practices based on the survey of 24 patient files she reviewed. She is expected to testify that in general Dr. Mirilashvili acted in accordance with usual professional practices – *i.e.*, as a medical professional, not a drug dealer – regarding the treatment of chronic pain and prescribing opioids together with other medications and referrals for other medical treatment and physical therapy.

To the extent that some of the medical records indicate conduct below certain levels of standard of care, Dr. Warfield is expected to opine that to a reasonable degree of medical certainty, Dr. Mirilashvili's efforts are still clearly within the broader range of a medical professional engaged in the usual course of professional practice. Her opinion in this regard is based upon evidence of:

- The establishment of doctor/patient relationships;
- Performing examinations;
- Taking general medical histories;
- Interpreting diagnostic tests;
- Recording patient records;
- Not taking directions from patients as to what to prescribe;
- Consulting PMP databases and conducting toxicology tests;
- Obtaining Patient Responsibility Agreements for Opioid-Based treatments;
- Referring patients to in-house physical therapy and outside medical care to orthopedic and other medical providers;
- Performing nerve conduction studies and EMGs.

As discussed, we will also be providing a supplemental summary of Dr. Warfield's opinions and conclusions about Dr. Mirilashvili's practices with respect to the specifically identified patients exchanged between the parties.

Very truly yours,

/S/HEM

Henry E. Mazurek
Counsel for Defendant Dr. Mirilashvili

Encl.

BEST POSSIBLE PRACTICE

AVERAGE PRACTICE

BELOW AVERAGE PRACTICE

} Standard of Care

MALPRACTICE

OUTSIDE OF USUAL COURSE OF PROFESSIONAL PRACTICE AND NOT FOR A LEGITIMATE MEDICAL PURPOSE: DRUG DEALING

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